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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,344	05/05/2006	Florence Henry	C 2892 PCT/US	6599

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EXAMINER
CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
03/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/578,344	HENRY ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-15* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Dec. 14, 2009 has been entered.

Currently, Claims 1-5 and 7-15 are pending. Claims 1-5, 7 and 8 are examined on the merits. Claim 6 is canceled.

The declaration of Marie-France Zambaux filed Dec. 14, 2009 has been considered.

Election/Restrictions

Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Feb. 28, 2008.

Applicant's election with traverse of Group I and the species schizandrin and a stabilizer, in the reply filed on Feb. 28, 2008 is acknowledged.

Newly submitted claims 12-15 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Group I (Claims 1-5, 7-8) is a composition comprising extract from the fruit of Schisandra chinensis and Group II (Claims 12-15) is a method of protecting human skin from ageing. Human skin protection can be done with aloe vera juice.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Newmark et al. (US 6242012 B1).

Newmark et al. teaches an orally administered herbal composition comprising schizandra berry extract, shizandrins (Claim 1) in a form for oral delivery (Claim 2). The composition can be in combination with a pharmaceutically acceptable oral, topical or parenteral carrier (column 3, lines 62-64). The supercritical extraction is disclosed for extracting schizandra berries (column 4, lines 27-29). Supercritical extraction involves extracting the ground herb with supercritical fluid carbon dioxide under pressure of from about 400 bar to about 600 bar and at a temperature of from about 80-120 degree Celsius (column 5, lines 44-48). Schizandra berries are Schizandra chinensis (column 5, line 1). Pharmaceutical carriers include stearic acid and magnesium stearate or gums (column 6, lines 59-62), which are stabilizers (see Applicant's Specification, page 18, lines 24-25). The composition may take the forms as suspensions, solutions or emulsions in oily or aqueous vehicles and may contain formulating agents such as stabilizing, suspending or dispersing agents (column 7, lines 56-58). Thus, auxiliary agents are taught. The treatment for human skin or melanin inhibition is taught because the composition is the same and would function the same.

Claims 1-2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhao (US 6605305 B2).

Zhao teaches a composition comprising an extract of the fruits of Schisandra chinensis containing schizandrin and a stabilizer (namely ascorbic acid). See Example 3. Because the product, schizandrin and a stabilizer, is claimed by the Applicant, the

product anticipates the claim. The process of obtaining the product does not chemically change the schizandrin and stabilizer.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, and 7-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sung et al. (WO 01/41778 A1) with Simoulidis et al. providing evidence of inherent characteristics.

Sung et al. teaches melanin inhibition compound containing gomisin N or gamma-schizandrin (Abstract), which can be extracted from Schisandra (page 5, lines 19-21). Schisandra chinensis is abbreviated as Schisandra, which is known by the

name Gomishi (see Specification, page 1, lines 22-31). The whole plant would contain the fruit because fruit is part of the plant. The invention can be used as a cosmetic and pharmaceutical whitener (page 6, lines 1-2). Schizandrin is dissolved in methanol and linoleic acid (page 6, lines 20-21), which is a stabilizer (see Simoulidis et al. Abstract).

The claims are drawn to a composition comprising schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid as the active ingredient therein, within a product-by-process claim.

The cited reference teaches a composition (including in pill/tablet form) consisting of (or consisting essentially of) an extract of Schisandra chinensis as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed Schisandra chinensis extract composition (including inherently comprising the instantly claimed levels of schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid. Since both were prepared using the same extracted chemical from the same plant (including the same essential plant) and concentration steps, and both demonstrate the same/similar activity with respect to melanin inhibition and whitening effect (see Applicant's Claims 4 and 8). Consequently, the instantly claimed Schisandra chinensis extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed composition is not identical to the referenced Schisandra chinensis extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is

claimed are considered to be so slight that the referenced Schisandra chinensis composition is likely to inherently possess the same characteristics of the claimed Schisandra chinensis composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed Schisandra chinensis composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., forming a topical or other commonly employed pharmaceutical form comprising a result-effective amount of the Schisandra chinensis extract beneficially taught by Sung et al. therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the Schisandra chinensis extract within Applicant's composition differ and, if so, to what extent, from the levels within the Schisandra chinensis extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the

prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sung et al. (WO 01/41778 A1) in view of Simoulidis et al. and further in view of Kim et al. (1999, J Chromatographic Science, 37: 457-461).

Sung et al. teaches melanin inhibition compound containing gomisin N or gamma-schizandrin (Abstract), which can be extracted from Schisandra (page 5, lines 19-21). Schisandra chinensis is abbreviated as Schisandra, which is known by the name Gomishi (see Specification, page 1, lines 22-31). The whole plant would contain the fruit because fruit is part of the plant. The invention can be used as a cosmetic and pharmaceutical whitener (page 6, lines 1-2). Schizandrin is dissolved in methanol and linoleic acid (page 6, lines 20-21), which is a stabilizer (see Simoulidis et al. Abstract).

Kim et al. teaches extraction of fruit of Schisandra chinensis by supercritical carbon dioxide and carbon dioxide modified with ethanol to enhance the yield of schisandrin four times when compared with pure carbon dioxide (Abstract). Supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Introduction, right column, paragraph 1). Ethanol is an auxiliary solvent to extract components.

The combined teachings of Sung et al. and Kim et al. teach a composition comprising a supercritical extract of the fruit of Schisandra chinensis and at least one of a combination of a stabilizer/solubilizer /biogenic active ingredient. The combined references do not pecifically teach incorporating the composition into a cosmetic/dermopharmaceutical preparation for treating UV radiation damage on human skin. However, it would have been obvious to add the composition taught by the combined references to a cosmetic/dermopharmaceutical preparation because Sung et al. suggests that compositions comprising schisandrin-containing extracts are useful in

the making of cosmetic preparations intended for inhibiting melanin synthesis. Kim et al. teaches extraction of fruit of Schisandra chinensis by supercritical carbon dioxide and carbon dioxide modified with ethanol to enhance the yield of schisandrin four times when compared with pure carbon dioxide (Abstract). Thus, at the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation that incorporating the composition from supercritical solvent extraction as taught by the combined references of Sung et al. and Kim et al. would provide the instantly claimed invention because Sung et al. demonstrated the beneficial functional effect of schisandrin and/or gomisin N to exert activity against melanin synthesis; and, suggested incorporation of the claim-designated compounds per into cosmetics for use in methods of whitening the skin or inhibiting melanins synthesis.

Claim Rejections - 35 USC § 103

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012 B1) in view of Kim et al. (1999, J Chromatographic Science, 37: 457-461) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Newmark et al. teaches supercritical extracts of schizandra berry composition (Abstract) schizandra has schizandrins (column 1, line 46), for oral administration or

topical administration as a cream (column 3, lines 66-67), with conventional pharmaceutical carriers; aqueous powder or oily bases; thickeners and the like may be necessary or desirable (column 7, lines 41-47). Pharmaceutical carriers such as stearic acid, magnesium stearate or gums (column 6, lines 59-62), which are stabilizers (see Applicant's Specification, page 18, lines 24-25). The composition may take the forms as suspensions, solutions or emulsions in oily or aqueous vehicles and may contain formulating agents such as stabilizing, suspending or dispersing agents (column 7, lines 56-58). Thus, auxiliary agents are taught. Schizandra extract would intrinsically contain schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid. Topical administration would imply use on skin and the effect of the composition would function as claimed because the source of the extract and form of administration are the same.

However, it does not teach supercritical solvent extraction.

Kim et al. teaches extraction of fruit of Schisandra chinensis by supercritical carbon dioxide and carbon dioxide modified with ethanol to enhance the yield of schisandrin four times when compared with pure carbon dioxide (Abstract). Supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Introduction, right column, paragraph 1). Ethanol is an auxiliary solvent to extract components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use supercritical solvent extraction because supercritical fluids

have advantages of increasing yield, shortening extraction times, enhancing selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Kim et al., Introduction, right column, paragraph 1). One would have been motivated to make extract with supercritical solvent for the expected benefit of increasing yield, shortening extraction times, and enhancing selectivity as taught by Kim et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

The reference does not teach all the ingredients in one composition. However, the reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

Applicant argues that Newmark teaches away from the supercritical extraction.

In response to Applicant's argument, Newmark et al. teaches supercritical extracts of schizandra berry composition (Abstract). The extract can be prepared using either a supercritical extraction process or conventional extractions (column 4, lines 27-30). Even though regular extract is preferred, the reference does teach schizandra can be extracted with supercritical extraction process. Thus, there is no teaching away.

The declaration of Marie-France Zambaux has been considered but it does not overcome the rejection because the unexpected result is not commensurate in scope with the claimed invention. The doses of schizandra extract are not part of the claim; thus, the unexpected result is not convincing.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michele Flood/

Primary Examiner, Art Unit 1655